THE SOURCE

THE MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

Spring 2010

STATES AND COUNTRIES TO WATCH IN 2010

Industry Implements Cross Donation Management Standard

Interview with Patricia A. Bryant, Executive Director GBS/CIDP Foundation International

Marcucci: A Well-Known Name in Different Parts of the World

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In the interest of encouraging broad and open discussion of issues relating to plasma protein therapies, collection and fractionation, **the Source** *magazine may contain statements of opinion on such issues. These statements are those of the author and do not necessarily reflect the opinion of PPTA or its members.*

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INSIDE

SPRING 2010

THE MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

In My View

Jan M. Bult
PPTA President

WHO should provide Guidance on Quality and Safety of Blood Products

THE WORLD HEALTH ORGANIZATION (WHO) is recognized worldwide, especially in its guiding role for developing countries. Because WHO is a prominent source of information, it is important that documents from WHO provide clarity and guidance and not create confusion. In May 2009, the Executive Board of WHO examined the availability, quality and safety of blood products. Blood products were defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products. On January 22, a report was issued with more details. Although comprehensive, this report contains information that is sometimes based on unsupported assumptions and biased position statements.

Anyone involved in our sector knows the difference between whole blood and plasma-derived medicinal products. Combining labile products (blood products for transfusion in hospitals) and stable products (finished therapies after a long manufacturing process) into one category is problematic. Everything is different: collection, testing, manufacturing, regulations, administration and more. Why issue a report that combines both and creates this confusion?

WHO recognizes that all therapies save lives and dramatically improve the quality of life of millions of people. It is also understood that, *"there have to be effective policies, strategies, quality systems, legislative and regulatory frameworks in the collection, testing, processing and supply of blood components, such as red cells, platelets and plasma, for clinical use."* I agree.

Then the report states, *"These safeguards are also crucial in the preparation of plasma for fractionation, as a raw material for the manufacturing of plasma-derived medicinal products, such as blood coagulation factor concentrates and immunoglobulins, which are on the WHO Model List of Essential Medicine...Recognizing the high risk of transmission of pathogens through transfusion of contaminated blood products...the Health Assembly...urged member states to promote the development of national blood services based on voluntary non-remunerated donation...These actions are complementary to the equally essential goal of improving overall good manufacturing practices."* How can the WHO combine how a donor is compensated with good manufacturing practices? Furthermore, the report states, *"Developing countries are facing serious shortages of all products, and have a much higher risk of transmission of pathogens."* What we see in many WHO documents is that this kind of information always leads to the standard sentence (and no surprise, it is here again) *"The provision of blood and blood products from voluntary, non-remunerated donors must be the aim of all countries."*

Why does WHO do that? How can you in one report state that coagulation factors and immunoglobulins are on the "List of Essential Medicines," knowing that the availability and supply would be dramatically reduced by applying this goal linked to the remuneration status of the donor? Do the people that write these policies really care about patients or are they just interested in pursuing political ideologies?

What is critically important is the development of stringent regulatory environments with oversight that ensures that collection, testing and manufacturing are done appropriately in all countries. Having these standards in place will guarantee that effective, safe lifesaving therapies will be more widely available. This is already the case in multiple regions of the world.

The report states further: *"The limited availability of plasma-derived products in developing countries stems from various causes...Large percentage(s) of plasma collected in developing countries is categorized as waste material and destroyed...*

This occurs because appropriate technology, regulatory controls, quality systems and good manufacturing practices are all lacking, thereby rendering the plasma unsuitable for conversion into fractionated products. Unless this situation is improved, plasma from developing countries will continue to be rejected for contract programs in a regulated environment."

This statement underlies the most important concept. The current, inadequate systems in most developing countries are responsible for shortfalls in plasma, not the remuneration sta-

How can you in one report state that coagulation factors and immunoglobulins are on the "List of Essential Medicines," knowing that the availability and supply would be dramatically reduced by applying this goal linked to the remuneration status of the donor?

tus of donors. Interestingly, all the donations in this case meet the WHO criteria for non-remunerated donors, but the quality is what makes it unsuitable for fractionation.

I agree wholeheartedly with this quote, *"It can therefore be assumed that blood services in developing countries would likewise benefit from the introduction and enforcement of the appropriate quality systems and independent and transparent quality-assurance regulations and inspection procedures."* Every member of PPTA has these systems in place and supplies safe and effective therapies all around the world.

The Director General of the WHO established a blood safety program in the late 1980's. In the year 2000, Blood Safety was declared an Organization-wide priority. The Secretariat initiated a major program to support the development of high quality systems for all aspects of blood transfusion through the global quality management program. In 2005, the WHO Blood Regulators network was established to define WHO's leadership role in supporting developing countries' regulatory authorities, which formulate regulations for the manufacture of blood products. At the present time, the results of these meetings have not been made public.

By definition, how can any agency claim a leadership role with a policy of following others? I think the WHO should demonstrate support for countries with regulatory agencies who have established their credibility and assist those countries in bringing these regulations to other (developing) countries.

This report also describes WHO's establishment of the Global Collaboration of Blood Safety—a mechanism for international collaborative relationships and partnerships with organizations and institutions working for global blood safety. I can proudly state that PPTA has been an important member from the group's inception. So, too, are many other organizations such as the World Hemophilia Federation (WHF) and the International Patient Organisation for Primary Immunodeficiencies (IPOPI). I remember that when IPOPI was admitted a few years ago, some criticized IPOPI because of its statement that patients need therapies made from all sources (compensated and non-compensated donors). Why would any individual criticize patients who receive safe and efficacious therapies made from voluntary compensated donors?

These statements from the WHO's report require close examination, *"...plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines and (the WHO is conscious) of the need to facilitate access to these products by developing countries"*

"The WHO is concerned by the unequal access globally to blood products, particularly plasma-derived medicinal products, which leaves many patients in need of transfusion and with severe congenital and acquired disorders without adequate treatment."

"Recognizing that the capacity to collect plasma is limited and would not suffice to produce enough essential medicines to cover global needs, it is essential that all countries have local capacity to collect plasma of acceptable quality and safety from voluntary and unpaid donations in order to meet their needs."

WHO should be commended for taking steps to improve the world's blood safety but it also should:

- Accept that labile and stable products are different and not be part of one Guideline;
- Accept that finished products made in countries with strict regulatory oversight are safe, irrespective of the donor remuneration status;
- Accept that there is no difference in the finished therapies made from voluntary paid and voluntary unpaid donors;
- Understand that self-sufficiency programs work well for National Blood Programs;
- Accept that self-sufficiency programs do not work well for finished products; and

Accept that the recognition and handling of individuals who donate is very important both for blood AND plasma donors.

PPTA is ready to assist wherever we can and will continue as a constructive member of the WHO's Global Collaboration for Blood Safety.

Level Playing Field III

By Jan M. Bult

LAST YEAR, I WROTE TWO COLUMNS IN THIS MAGAZINE that brought attention to Sanquin, based in The Netherlands, and that provided examples of questionable business practices by the company. I mentioned tax-exemptions, relative high costs for labile products, (cross) subsidies and unfair competition. It was no surprise that Sanquin responded and, in the spirit of transparency, the Sanquin response was published in its entirety in *The Source* magazine. Nothing was written that questioned the facts that I used in the writing.

Subsequently, Dutch Members of Parliament asked questions in the Parliament. The Minister of Health instructed that an investigation was needed to compare the prices of labile components with other countries. On February 4, 2010, the Minister of Health wrote to the Parliament, and the survey results became public. The letter from the Minister and the survey are revealing and confirm many of the facts:

- An international benchmark on prices of labile products was done and studied The Netherlands, France, Finland, Ireland and the French part of Belgium; and
- "The prices of short acting blood products for hospitals in The Netherlands are relatively high compared to the other studied countries, prices of plasma for fractionation are relatively low. The report shows a negative margin on the sales of plasma to the private Division. This means that the public part of Sanquin is having a loss favoring the private part of Sanquin.

  De prijzen van korthoudbare bloedproducten zijn in Nederland voor ziekenhuizen relatief hoog ten opzichte van de andere onderzochte landen, plasmaprijzen ten behoeve van fractionering zijn relatief laag. Uit het rapport blijkt dat er sprake is van een negatieve marge op de verkoop van plasma aan de private divisie. Dit betekent dat de publieke tak van Sanquin een verlies draagt ten gunste van de private tak van Sanquin.
- Prices for plasma for fractionation (internal pricing) on average are 12 percent lower than the pricing in the compared countries.
- The results of the study were reason for the Minister to ask Sanquin to increase the price of plasma for fractionation with 12 percent.
- Normally prices for short acting blood products are increased annually, however, because of the increase of the price for plasma, increases for short acting products will be less than the index.
- The Minister intends to change the annual report of Sanquin to create more transparency in the cost structure of Sanquin.
- The price increase of plasma for fractionation to the average of the other countries will only partly remove the negative margin.

In the columns in this magazine and in meetings with parliamentarians and in presentations at public meetings, we have repeatedly pointed out the multiple signs of cross-subsidy. Charging higher prices to hospitals for labile products resulting in artificially low acquisition prices for plasma is not right. It is called unfair competition and a legal challenge. The Dutch Minister of Health deserves a compliment for addressing this issue and ask for more transparency. The report clearly confirms what we have been saying all along. Costs are allocated to the labile components, hospitals pay for it and the acquisition cost of the plasma for fractionation is artificially low.

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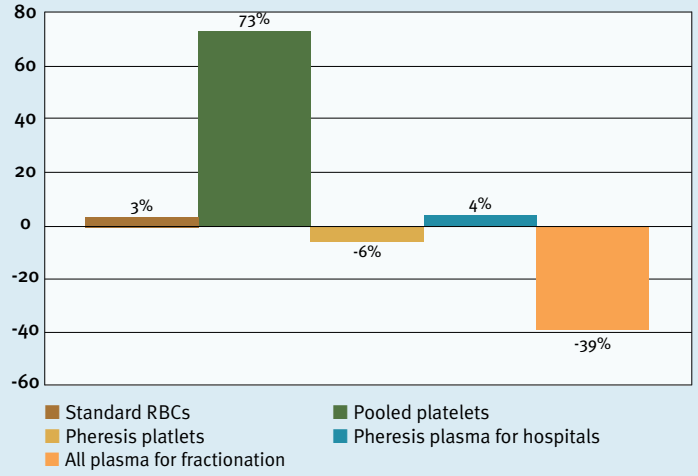
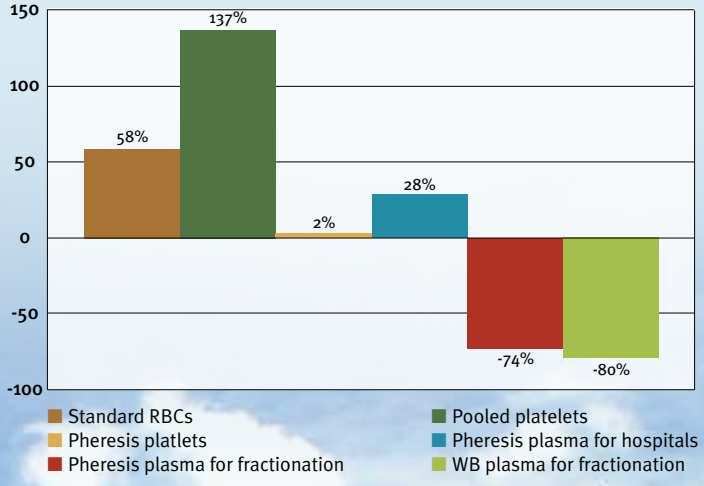
Net Margin Per Product with Classical Cost Allocation Model



Net Margin Per Product



Source: Europese benchmark Kort houdbare bloedproducten-Ministerie van Volksgezondheid Welzyn en Sport

It is important to also point out that the survey has its limitations:

- Ireland and Finland have no manufacturing plants;
- The plasma for fractionation from the French part of Belgium is going to DCF-CAF where Sanquin is the majority owner;
- Belgian plasma for fractionation is subsidized at 25 Euro per liter. This money comes from an increase in liability insurance premium for car owners; and
- France provides plasma only to the French company LFB, also a 25 percent owner of DCF-CAF.

Sanquin is a respected company and manufactures good therapies for many patients. Sanquin is a competitor and there is nothing wrong with that. Competition should be encouraged. But the same rules should apply for all manufacturers. We need a level playing field. Yes, I know some believe that Sanquin is facing a more challenging business environment, but that is what competition is about. The loss of the toll fractionation contract with Finland to one of our members is another complicating factor for Sanquin. Our members continue to invest in product safety, quality and yield and spend serious amounts of money in research in many areas. Finland made a decision to move to a company with a higher yield, because it felt that from an ethical standpoint, it is important that the maximum amount of product is produced using the valuable plasma of Finnish donors.

I will keep you informed.

The Parliament of the Netherlands in The Hague.

Industry implements Cross Donation Management Standard

By Joshua Penrod

THE INDUSTRY HAS BEGUN IMPLEMENTATION of the new Cross Donation Management Standard (CDMS) under the International Quality Plasma Program (IQPP). The CDMS is the first new addition to IQPP in several years, and was authored by the IQPP Standards Committee and approved by the Source Board of Directors. Industry members and others contributed comments during the open comment period in autumn of 2009. We would like to thank all those who offered their input.

The CDMS focuses on exchanges of information between donor centers in a Donor Recruitment Area. These exchanges of information are related only to new donors who present for donation in a given center, which will then seek confirmation from a neighboring center as to whether the donor donated or not and, if so, in what time period. This helps to ensure that the donor is donating within the regulatory limits and is intended as an additional level of donor safety. The CDMS will work in concert with existing measures that centers may take to help ensure donor health and any new measures that centers may adopt in the future.

As the implementation period progresses, PPTA and members of the IQPP Standards Committee will be monitoring the CDMS and managing any issues that arise. It is expected that the CDMS Implementation Period will end in August, 2010. PPTA and the IQPP Standards Committee will also be tracking the industry's compliance with the Standard throughout the period in order to anticipate any other challenges that may arise.

We are very pleased to have developed this new Standard and are looking forward to its implementation. It is a demonstration of the industry's willingness to go beyond the minimum requirements of the regulatory sphere and be proactive according to its two greatest areas of importance: product safety and quality, and health of the donor, with the latter being the focus of the new CDMS.

Joshua Penrod *is PPTA's Vice President, Source*

PPTA to Host Donor History Questionnaire Implementation Workshop on June 14, 2010

PLAN TO ATTEND PPTA's Donor History Questionnaire (DHQ) Implementation Workshop on Monday, June 14th in conjunction with the 2010 Plasma Protein Forum at the Hyatt Regency in Reston, VA.

After many years of work by PPTA staff and its Donor History Task Force, the U.S. Food and Drug Administration (FDA) provided preliminary approval for the PPTA DHQ in October 2009. The PPTA DHQ contains a full length and abbreviated standardized donor history questionnaires. These documents may be used by members to help streamline the donor screening process. Companies that wish to implement the PPTA DHQ before issuance of FDA final guidance may do so upon filing a Prior Approval Supplement (PAS).

In anticipation of final guidance, PPTA is holding a workshop that will cover an array of topics related to the PPTA DHQ and its corresponding documents. The agenda will include information on the format of the PPTA DHQ and how to implement its use, including presenting it on an automated DHQ platform, PPTA's role in maintaining the PPTA DHQ, and regulatory expectations. Look for a complete agenda soon!

To register for this workshop, please visit www.pptaglobal.org. Please contact Bridget Elis, belis@pptaglobal.org for more information.

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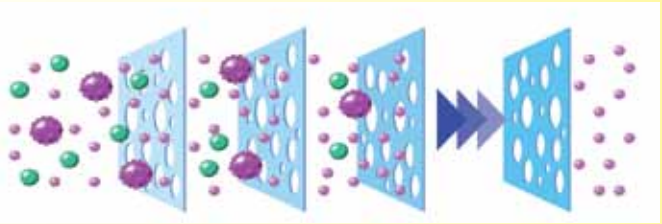

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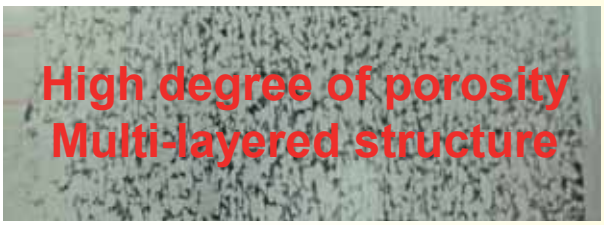

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Above Left: Andrea Marcucci, Giovanni Rinaldi and Paolo Marcucci.
Above Right: Giovanni Rinaldi, Guelfo Marcucci, Paolo Marcucci and Jan M. Bult at Il Ciocco.
Background Photo: An Aerial view of Tuscany, Italy.

MARCUCCI:

A WELL KNOWN NAME IN DIFFERENT PARTS OF THE WORLD


Guelfo Marcucci and Jan M. Bult

By Jan M. Bult

In 1992, a few industry leaders met in Geneva to discuss the need to create an association to work on the complex issues this industry was facing. One of them was Guelfo Marcucci, father of Kedrion's current President, Paolo. The decision was made to establish the PPTA's predecessor, the International Plasma Protein Industry Association (IPPIA). Guelfo Marcucci started his company more than 50 years ago. Marcucci is a famous name, and the family history reveals a lot of interesting things.

Guelfo retired in 2000 to live in his beautifully located hotel Il Ciocco close to Lucca in Tuscany, Italy. Kedrion headquarters are within walking distance. The view from the mountain is unique and a great reward for his hard work. I met the Marcucci family a few months ago and learned a lot about the family.

Close to Lucca is a small town called Barga. This is where the Marcucci family lived in the nineteenth century. His grandfather moved to the United States around 1890 to start a new future with all his children. One of them, Marianne Marcucci, married Alessandro Gonella, who gave his name to Gonella bread, a well-known brand name in the Chicago area. Guelfo's father could not forget his love for Tuscany and went back to Italy, married and taught his children to work hard.

Guelfo Marcucci began to deal with pharmaceuticals in 1953 when he took over a small company producing generics where he was joined by Leo Marcucci and Edo Rinaldi. Two of their sons, Paolo Marcucci and Giovanni Rinaldi, currently have leadership roles within the company.

In the 1960's, the company started to look at biologicals and came in contact with Immuno in Vienna. This resulted in the Marcucci Group becoming the distributor of immunoglobulins in Italy for Immuno. When the company decided to start making their own immunoglobulins, the agreement was terminated, and Immuno started its own company in Italy.

It is interesting to know that the plasma the Marcucci company used in those years was based on the Merieux technology, which used plasma from placentas. Later that changed, and the company started using plasma from U.S. donors.

The company grew and developed their business by setting up multiple companies in Naples, Bolognana and Rieti. Guelfo and his wife raised three children, Paolo, Andrea and Marialina. Paolo and Andrea are active within the current Kedrion company, while Marialina works in public relations.

Paolo and Andrea have had quite different careers. For several years, Paolo had been the head of a private television channel and lived in London between 1988 and 1992. Andrea embarked on a political career and was a Member of Parliament from 1992 to 1994, then in 1996 he joined the pharmaceutical company as CEO. In 2006 he was appointed Undersecretary of Culture, and in 2008 became a Senator. Today he also holds the position of President of Haemopharm.

When Paolo became the CEO, he developed a vision that embraced quality improvements to meet the international challenges. Together with Giovanni Rinaldi, a well-respected businessman with a good knowledge of the industry, he leads a company that demonstrates its commitment to producing life-saving therapies for patients around the world. In December 2009, the company passed the inspection for PPTA's Quality Standards of Excellence, Assurance and Leadership (QSEAL) certification, so now it is a proud member of the QSEAL family. PPTA is proud of having Kedrion as one of its important members.

Jan M. Bult *is PPTA's President*

STATE AND NATIONAL GOVERNMENTS AROUND THE WORLD have spent the last few years wrestling with the worst global recession in more than 50 years. This is causing decision-makers in some states of the European Union and the United States of America to consider cutting health-care costs when there are no more low hanging fruit to pick. These decisions could have a negative impact on patient access to plasma protein therapies in certain areas of the world. Governments with the worst deficits pose the greatest threat to patient access since they must cut the most funding from their public programs. All those concerned with patient access to their medically appropriate therapy must watch these governments closely to ensure patients are not denied access to their life-saving therapies.

States and Countries

United States

Medicaid is a federal-state partnership that provides health care to more than 57 million low income individuals in the United States. The federal government and the individual states pay for the Medicaid benefits jointly, but the individual states make the decisions about what benefits are provided and how much is paid, as long as the decisions meet minimum standards established by federal law.

As a result of their role in the Medicaid decision-making process, and the historic deficits states are facing, it is important to closely watch the states as they hold their legislative sessions this year. During these sessions, the states will decide if they should increase taxes or reduce spending. States that choose to reduce spending will have to reduce Medicaid spending, since it is the second largest portion of most state budgets.

Particular attention should be paid to California. The state's deficit is $6.6 billion for the current year, and $12.3 billion for the next fiscal year. As part of his numerous reductions necessary to balance the state's budget, Governor Arnold Schwarzenegger has proposed cutting Medicaid expenditures by $2.4 billion. Included in these reductions are utilization controls, provider rate decreases, and greater out-of-pocket costs for Medicaid recipients.

All of these cost-containment policies would have a negative impact on individuals that rely on plasma protein therapies. Utilization controls could involve step-therapy that would cause patients to switch therapies. Greater out-of-pocket costs could lead to patients not having enough money to procure their therapies or infusing less frequently than medically appropriate.

Similar cost-containment strategies are being considered by other states. Perhaps the greatest threat to patient access is the idea of sole-source providers for specialty pharmacies. Decision-makers in Iowa and Oregon have suggested the idea of having their Medicaid recipients receive their clotting factor from one supplier in one location in the state. PPTA is concerned that limiting Medicaid recipients to one provider would require individuals to switch providers and to travel a great distance to reach the sole-provider. This policy could result in increased Medicaid costs because of increased hospitalizations, if patients find the sole provider is too far to travel or in increased usage of Medicaid transportation services to bring the patients to the sole provider.

Europe

Its not just country-level changes that are being watched. The public health care systems of Europe are going to have to bear the major impact the financial reforms sweeping the continent as a result of the global financial upheaval over the last two years.

Unprecedented national borrowing will be repaid on the basis of reduced spending and increased taxation. Several countries that will be highlighted in this article are those thought to be particularly exposed and where extreme spending controls are expected.

Signs of tighter spending on health are increasingly evident. Tighter controls in clinical guidelines, simple and strict caps to spending on certain high cost medical conditions, higher pharmaceutical taxes and single supplier contracts are just examples of the tightening of the fiscal purse strings.

Portugal

Portugal, the westernmost country of continental Europe, is best known for its beautiful sunny beaches and golf courses. Although it has been qualified as being among the top 20 countries in the world in terms of quality-of-life, the Portuguese economy, after having known a significant growth in the 1980s and 1990s, has recently been struggling with financial debts. Portugal officially has the lowest per capita gross domestic product (GDP) in Western Europe and has recently been described by *The Economist* as the "new sick man of Europe."

Despite the poor status of its general economic situation,

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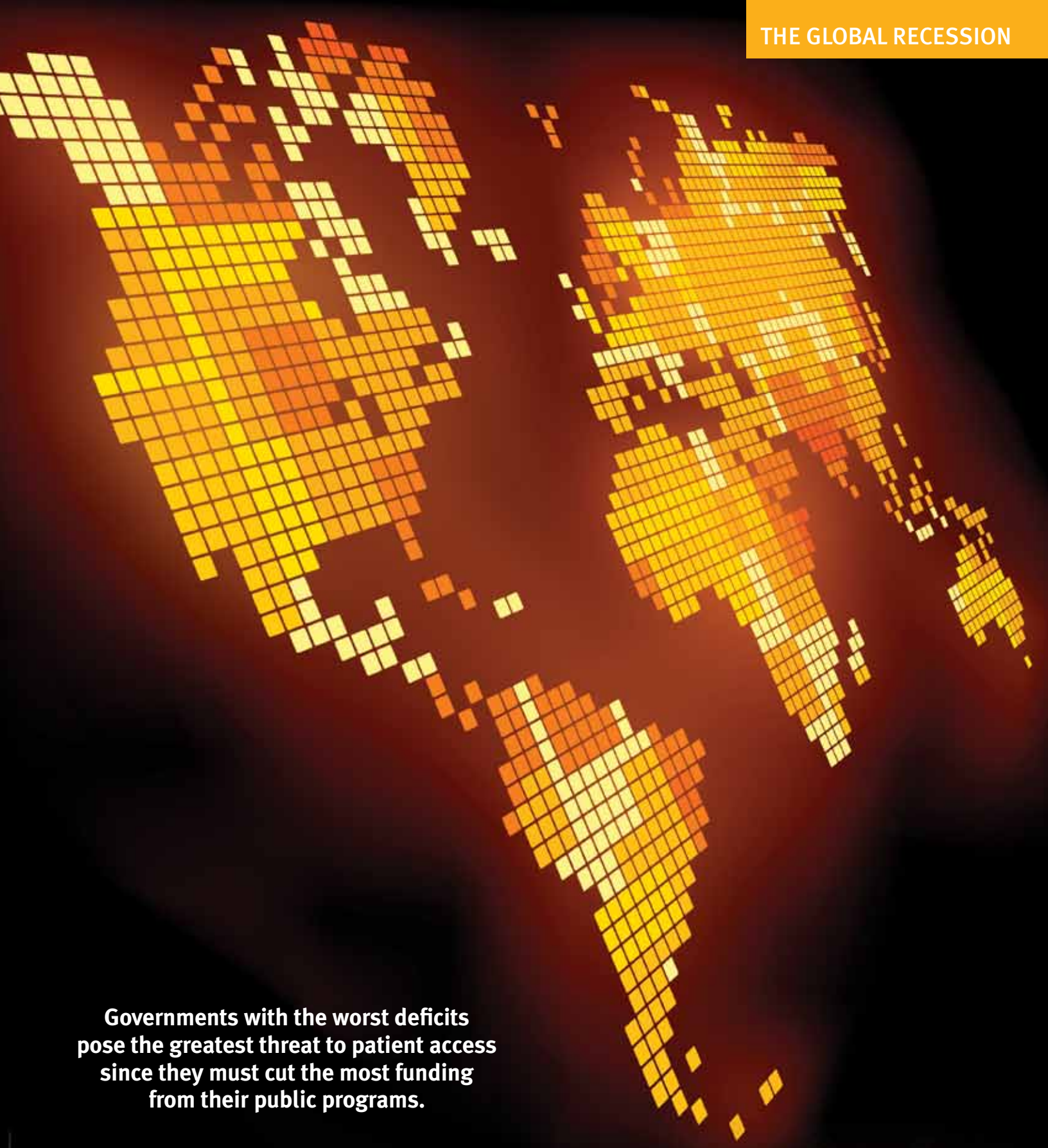


Governments with the worst deficits pose the greatest threat to patient access since they must cut the most funding from their public programs.

TO WATCH IN 2010

By Johan Prevot, Laura Savini, Bill Speir, Ilka von Hoegen and Charles Waller

patient access to plasma protein therapies has been improving in recent years and the treatment levels of patients affected by conditions such as hemophilia and primary immunodeficiencies have therefore been increasing. Portugal imports plasma protein therapies from PPTA companies and reportedly collects around 30-40.000 liters of recovered plasma per year although this plasma has been wasted in the past as it failed to meet European Union (EU) regulatory requirements in terms of quality. However the quality of Portuguese plasma has recently improved and collecting organizations are increasingly receiving EU certification. In 2009, a first-ever toll fractionation call for tender was organized but ended up being cancelled for logistical and organizational reasons.

Similarly, the current hospital purchasing framework for plasma protein therapies has been identified as an issue of concern by PPTA. An official statement from the authorities recently announced the cancellation of the national tender for plasma protein therapies launched toward the end of 2008. It seems that it is unlikely that another tender will be launched any time soon but also that there is no alternative clear framework on how appropriate patient access to plasma protein therapies will be guaranteed.

These issues highlight the need to monitor the Portuguese situation closely in 2010. PPTA has recently launched a Portugal Task Force through which these issues will be addressed.

Greece

The poor fiscal health of Greece has been a main concern for the European Commission and other European Member States during the last quarter of 2009. This worry increased with the country's inability to cut its deficit and service a massive debt load. Concretely, many companies have been affected by extremely long delays in payments from public Greek hospitals of three years and sometimes as much as five years. This has prompted them to inform relevant stakeholders about the threat to sustained access to plasma-derived medicinal products.

Last December 31, 2009, public hospital debts for medicines, including plasma proteins, for goods invoiced before June 2007 were paid. At the same time, it was announced that public hospital debts for pharmaceuticals invoiced prior to the end of 2008 will be cleared by the end of March 2010. Moreover, at the beginning of February 2010, the European Commission approved the new Stability and Growth Program submitted by Greece in January 2010. This plan contains a section focusing on public debt reimbursements outlining the government commitment to bring reimbursement delays up to European standards. Although there seems to be an improvement, PPTA will monitor closely the evolution of the economic and financial situation and the reimbursement delays in 2010.

Italy

Until 2005, Italian plasma had to be completely fractionated within Italy. The 2005 fractionation law widened and removed this restriction, but before coming into effect a separate law, implementing the 2005 law was needed. In 2009, a draft of this implementation law was presented to the Italian Parliament. Instead of completely opening the fractionation to all respected and qualified fractionators, as European Community law requires, it was proposed to take a first step and only open the market to three named fractionators, and specifically excluding other organizations.

Only companies that invest and provide employment in Italy or companies from countries that adhere to the voluntary unpaid donor principles would be permitted to tender for Italian plasma when the new law comes into effect. There is a weak stated intention to review and revise the law three years after it comes into effect and to allow all companies to tender for Italian plasma.

However, an opinion of the Italian Anti Trust authority questioned the legality and compliance of the draft law with Italy's other legal obligations. On the other hand, pressure from the influential Italian donors' associations has affected and continues to affect decision making in this area.

In the Senate Commissions, it was correctly proposed to notify the European Commission of the proposed new text. In addition, pursuant to article 2 of the GATT-TBT Treaty, Italy is also obliged to perform a similar notification to the World Trade Organization (WTO).

However, during the session of the 14th Senate Commission which took place in January 2010, the proposed notification to the European Commission was eliminated from the text.

PPTA continues to believe that the best way to ensure that Italian plasma for fractionation provides the maximum benefits to Italian patients is through extracting the most plasma derivatives possible. The three fractionation companies "preferred" in the legislation each use very high standards. They are highly valued members of PPTA. However, the draft law could result in time delaying litigation, if the draft law is not amended to comply with Italy and European treaty obligations. Through open tendering, Italian donors and patients can be sure that full use is made of Italian plasma.

Johan Prévot *is PPTA's Director, Health Policy, Europe;*
Bill Speir *is PPTA's Assistant Director, State Affairs;*
Laura Savini *is PPTA Europe's National Affairs Assistant;*
Ilka von Hoegen *is PPTA's Senior Director, Quality and Safety and* Charles Waller *is PPTA's Vice President, Europe.*

Germany's Progres Treating Rare

By Norbert Fuchs and Sybille Beck

THE START OF THE GERMAN HEALTH CARE SYSTEM is originally associated with the introduction of the statutory health insurance under Chancellor Otto von Bismarck in 1883. Understanding its complexities and structure requires awareness of the sociopolitical priority to have an inclusive system with insurance for all and especially the working population. Societal changes and scientific developments since the 19th century have driven a dynamic process to reform and improvement resulting in a (patient) population predisposed to regular and even fundamental change.

The current situation...

One of the most remarkable characteristics of the German system is the strict distinction between outpatient and inpatient treatment, whereby the outpatient treatment is—historically and politically— the one to be preferred. As a result the financial resources allocated to the two sectors are strictly separated as well, and the options of hospitals to treat patients on an outpatient basis were traditionally very limited. Medical and scientific progress made it obvious that for certain diseases a special form and a special infrastructure had to be found to provide patients with more complex, serious and often chronic disease care from one source.

The Health Modernization Act in 2004 allowed hospitals to apply for a special status, which would allow them—among other things—to treat patients in well-defined clinical areas. This new approach was further strengthened with the enhancement of Paragraph 116b SGB V (Code of Social Law V) in 2007. Table 1 gives a full list of the diagnosed conditions to which Paragraph 116b SGB V specifically applies and which are classified as follows:

- Diseases requiring highly specialized treatment;
- Rare diseases; and
- Diseases with special course of disease.

Table 1

DISEASES REQUIRING HIGHLY SPECIALIZED TREATMENT	RARE DISEASES	DISEASES WITH SPECIAL COURSE OF DISEASE
1. CT/MRT-based interventional pain-related performances	1. Cystic Fibrosis	1. Oncological diseases
2. Brachytherapy	2. **Hemophilia**	2. HIV/AIDS
	3. Patients with dysplasia, congenital deformity of the skeletal system	3. Serious courses of rheumatic diseases
	4. **Severe immunological diseases, e.g. PID**	4. Serious heart failure
	5. Biliary cirrhosis	5. Multiple Sclerosis
	6. Primary sclerosing cholangitis	6. Epilepsy
	7. Wilson's Disease	7. Cardiological diseases in children
	8. Transsexualism	8. Premature babies with secondary damages
	9. Children with specific inherited metabolic diseases	9. Paraplegia with complications requiring interdisciplinary care
	10. Marfan syndrome	
	11. Pulmonary hypertension	
	12. Tuberculosis	
	13. Neuromuscular Diseases	

MATTHEWLEESDIXON / ISTOCK, SHUTTERSTOCK, GOGLE

sive Approach to Diseases

The Joint Federal Committee has identified the scope, i.e. the indications, which fall under this regulation and critically reviews the list bi-annually. The Committee has also defined a number of prerequisites, which have to be fulfilled precisely in order to get approval of the authority responsible for hospital planning in that respective State. This approval grants the hospital cost-covering treatment of patients with such diseases from highly qualified, specialized and experienced physicians and medical staff. Primary immunodeficiencies exemplify best the great benefit and purpose of the Paragraph 116b SGB V legal provision. The unspecific heterogeneous symptoms presented by primary immunodeficiency disease (PID) patients typically result in a log period prior a conclusive PID diagnosis. The well documented patient histories show their long ordeal often start with the general practitioner and then may lead onto the Ear-Nose-Throat-specialist, or the pulmonologist, the gastroenterologist etc. during which time the patient continues in poor health. None of these experts has the appropriate qualifications, skills, appropriate diagnostic tools, or experience to diagnose PID. They will go on "mistreating" a patient suffering from a primary immunodeficiency.

The Future...

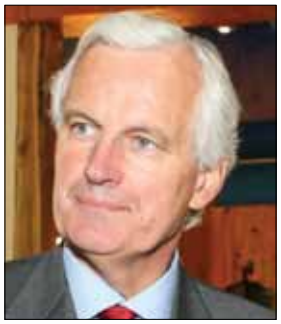
Paragraph 116b SGB V was opposed by the general practitioners and in particular by the specialists in private practice as they fear "losing" their patients and the related funding to the specialized treatment centers. They also regard the introduction of the "new" Paragraph 116b SGB V as competition with unfair measures. The most common argument is that hospitals can usually rely on financing through the provider, the health insurers and the state, whereas the physician in private practice bears the full financial risk; plenty of lawsuits have been conducted – so far without any tangible success or clarity.

The new German government consisting from the Christian-Democrats and the Liberals has announced their intention to carry out another fundamental health care reform, which will also impact Paragraph 116b SGB V. The Liberals in particular who provide the Health Minister are traditionally the party of the medium-sized businesses and the self-employed including physicians in private practice, hence, reforming Paragraph 116b SGB V will be welcomed by the natural constituency. Although patients and stakeholders have been reassured that the regulation as such will not be eliminated, it will certainly be amended. It is not pessimistic to expect that such an amendment might lead to a non-applicability, hence, quasi-elimination. The various stakeholder groups in these discussions—patients, physicians and PPTA—will be working to maintain the provisions of Paragraph 116b SGB V as they are to ensure optimal diagnosis and treatment for patients requiring more than standard care particularly PID patients and people with hemophilia.

Norbert Fuchs *is Director, Health Policy Central Europe with CSL Behring and* Sybille Beck *is PPTA's Senior Manager, Source Europe*

Pictured here: Berlin, Germany

José Manuel Barroso



Michel Barnier

John Dalli

Antonio Tajani

The European Commission

The Beginning of a New Era

BY JOHAN PRÉVOT

FIVE MONTHS AFTER THE EUROPEAN PARLIAMENT'S ELECTIONS in June 2009 and following his reappointment as President of the European Commission in September for a second consecutive five year term, European Commission President **José Manuel Barroso** unveiled the 'Barroso II' European Commission Designate in November 2009.


Maire Geoghegan-Quinn


Joaquin Almunia


Karel De Gucht


Herman Van Rompuyi


Baroness Catherine Ashton

Among the changes of key portfolios within the Commission, the appointment of Frenchman **Michel Barnier** as Commissioner for Internal Market and Services is probably the most controversial one after fears from other member states that Barnier's policies will not embrace the free economic market model.

Other key appointments relevant to the pharmaceutical industry are the appointment of **John Dalli** (Malta) as Commissioner-Designate for Health and Consumer Policy (Directorate-General (DG) Sanco), DG Industry and Entrepreneurship will now be under the responsibility of **Antonio Tajani** (Italy), **Maire Geoghegan-Quinn** (Ireland) will be in charge of Research, Innovation and Science while **Joaquin Almunia** (Spain) will head DG Competition and **Karel De Gucht** (Belgium) will be responsible for Trade.

Perhaps the most important change for the pharmaceutical industry in the structure of the new European Commission is the move of Unit F2 Pharmaceuticals from DG Industry and Entrepreneurship (previously DG Enterprise & Industry) to DG Sanco although responsibility for Competitiveness in the Pharmaceutical Industry and Biotechnology will remain with Industry and Entrepreneurship. Consequently, the European Medicines Agency (EMEA) will now be under the responsibility of the Health and Consumer Policy portfolio.

Many have welcomed this change and believe that with the responsibility for pharmaceutical and medical devices policies and for the EMEA too, the Health and Consumer Policy Commissioner will be better equipped to lead a consistent and coherent approach to public health policy and ensure better protection of patients and safety of medicines throughout the Union. However, doubts have also been raised on whether DG Sanco will be able to find the right balance between public health demands and the huge economic input of the pharmaceutical industry in the European Union's competitiveness.

The change also means that DG Sanco will now take over from DG Industry and Entrepreneurship the task of bringing forward the "pharmaceutical package" which includes a set of proposed regulations and directives on counterfeit medicines, patient information and pharmacovigilance. It is hoped that the move will not further slow down a process which has been proceeding at a much slower pace than it had been anticipated.

Two other significant nominations at the European level were revealed shortly after the people of Ireland said "yes" to the Lisbon Treaty during a second referendum in October 2009 and the subsequent entry into force of the treaty in December. The appointment of **Herman Van Rompuy** (Belgium) as the first permanent European Union President and **Baroness Catherine Ashton** (UK) as High Representative for Foreign Affairs and Vice President of the European Commission put an end to the constitutional turmoil which had fueled so many debates and discussions in the European Union in the last decade.

Last but not least, it has to be noted that even though the mandate of the current Commission ended on October 31, 2009, it will remain in place until the new College of Commissioners has been approved by the European Parliament and taken office in early 2010. Initially scheduled in late January 2010, the European Parliament's final vote on the full Commission has been delayed due to the unexpected withdrawal of the initial Bulgarian candidate as Commissioner designate for International Cooperation, Humanitarian Aid and Crisis Response.

Johan Prévot *is PPTA's Director, Health Policy, Europe*

ERICSPHOTOGRAPHY / ISTOCK, GOOGLE IMAGES

Patricia A. Bryant

Executive Director, GBS/CIDP Foundation International

AFTER A DIVERSE CAREER OF HELPING OTHERS and a frighteningly unexpected bout with Guillain-Barré Syndrome (GBS), Pat Bryant embraces the challenge of leading an international foundation, taking the reins from the group's matriarch, Estelle Benson, and using her personal and professional experience to guide the organization forward.

Tell us about your personal experience with Guillain-Barré Syndrome.

Life's journey is full of twists, turns and surprises. Who would have thought being diagnosed with a rare, paralyzing, frightening peripheral neurological disease would be the path to my present position as executive director of the GBS/CIDP Foundation International.

Patricia A. Bryant

Part of that journey began when I awoke on a Saturday morning in late January of 2003 and discovered that while I wanted to walk, my legs were not cooperating. I couldn't feel my feet and found I was unable to lift myself out of the chair where I had taken a moment to rest. I tried to walk down a few steps and my knees buckled. I chalked my weakness up to the fact that I was in bed for most of the previous week as a result of what was thought to be a virus. During that week, I had difficulty swallowing, had severe bouts of diarrhea and experienced severe back pains. I phoned my doctor to tell him of my weakness and numbness in my legs and hands. He urged me to go back to bed and rest. By this time, I could feel the paralysis ascending my body and could even feel it internally. The next morning, I was unable to walk without assistance, my back pains worsened and I was frightened beyond belief. Knowing that something serious was happening, I went to the emergency room (ER). The ER doctor who treated me suspected a heart problem and admitted me. The fact that I couldn't walk, had no feeling in my hands, couldn't swallow, and had no feeling in my bowels, etc. did not seem to be taken seriously. The next morning, I was sent home and was told to see my internist.

My friends literally had to drag me around because I could not stand or walk on my own. One of them rented a walker, so that I could at least balance myself. The following two weeks found me being shuffled from doctor to doctor, hospital to hospital for tests—magnetic resonance imaging (MRI), electromyography (EMG)—and still no definitive diagnosis. A physiatrist that I was referred to was the first doctor to check my reflexes. Of course, there were none. With each passing day I became weaker and more frightened. It seemed as if no one was listening to ALL of my symptoms and no one was able to connect the dots!

After two weeks, my body finally gave out completely, and I had to be taken by ambulance back to the hospital where I was first seen and discharged. Two doctors in the emergency room finally listened and told me that they believed I had Guillain-Barré Syndrome.

From the time of the onset of symptoms to the time I was diagnosed, I had not slept. I was emotionally and physically drained and thought that I was going to die. Even with a diagnosis, no one explained what was happening to me, nor my prognosis. Once admitted to the hospital, I began a five day regimen of intravenous immune globulin (IVIG). My swallowing difficulties continued, and I proceeded to quickly lose 35 lbs. I couldn't walk, had no use of my arms and hands, was extremely weak and had to depend on others for everything. Being an independent person, this was most difficult. I was convinced that I never walk again or be able to return to my normal lifestyle.

Hope finally came when a friend learned of my situation and phoned me in the hospital to tell me he knew of two men who had had GBS. They gave me a call and hearing them share their experiences with GBS and their words of encouragement gave me, for the first time since the nightmare began, a feeling of hope and encouragement. I could literally feel the anxiety leaving my body. While I realized that the road back from GBS was going to be long and meant five steps forward and three steps backwards, patience, a positive attitude and humor kept me focused and enabled me to take one day at a time.

During my first week in rehabilitation, one of the men with GBS who had called me was able to visit. Just seeing him walk through the door was the best medicine I could have been given. This person had experienced firsthand what I was going through and was standing in front of me sharing his story. There was a light at the end of the tunnel. What a blessing! I took each day in stride, working at my physical and occupational therapy, always trying to keep a very positive attitude. I firmly believed that this was happening to me for a reason. Little did I know that it would dramatically change the course of my life!

What led you to your new role as executive director of the GBS/CIDP Foundation International?

In my earlier professions, I always focused on improving the quality of life for others. For 20 years, I taught and was a school administrator. Then I worked for Catholic Charities to develop educational, job

training and health care programs for juvenile offenders. I also was an investor relations professional and, during that time, became hospice volunteer providing patient care. As part of hospice's speaker's bureau, I gave lectures on end-of-life issues and palliative care.

Having GBS led me directly to the Foundation. When recovering and when I had regained enough strength in my hands to wheel myself to a computer, I searched the Internet for "Guillain-Barré Syndrome." I had many questions about this disease and needed answers. Those answers came when I discovered the GBS/CIDP Foundation International. Immediately I registered and was sent a wonderful package of information that contained a directory of national and international chapters. I made arrangements to meet with the liaison for Nassau County, New York. After experiencing what a contact and a visit from a former GBS patient had done for me, I wanted to be able to give that same hope and support to others. I became a liaison for the Foundation and then took over as regional director for New York and New Jersey. In 2006, I became a member of the Board of Directors, and in May of 2009 assumed the position of executive director.

On a personal note, as a result of having GBS, my life made a 180 degree turn. It also was the catalyst that propelled me onto the dance floor. While I was struggling with the possibility that I could not and may not walk again, I thought of the times I wanted to take ballroom dance lessons, but kept putting it off. When I regained the use of my legs, I took myself to Arthur Murray and signed up for lessons. I was hooked, and since 2004 I have been dancing, competing and winning!

What are the Foundation's key priorities this year?

The Foundation's key priorities for 2010 are to continue to expand awareness of GBS, chronic inflammatory demyelinating polyneuropathy (CIDP) and variants, so that anyone afflicted will receive early diagnosis and dependable treatment. To this end, our medical advisory board is developing criteria in order to designate Centers of Excellence around the country. This will be a tremendous help to patients who need neurologists and neuromuscular specialists. Our organization will continue to be the catalyst for connecting people with similar experiences. We also will be redesigning and expanding our website. Our 11th International Symposium will be held November 5 to 7 in King of Prussia, Pennsylvania with attendees coming from as far away as New Zealand. Our organization continues to fund cutting edge research into these rare diseases. And, we are working to ensure that the needs of patients with rare diseases are addressed and that the current coverage and reimbursement policies of Medicare, Medicaid and third party insurers support the treatment and rehabilitation needs of our patients.

Tell us about your chief public policy goals?

To ensure that people afflicted with GBS, neuromuscular variants, and CIDP and their families have an active and strong voice in the nation's capital and state capitals across the country. Through awareness, education and outreach the Foundation and its members effectively promote the interests and concerns of the Foundation directly to our nation's elected officials.

I believe strongly in the importance of developing and successfully executing effective public policy/advocacy programs focused on research, early diagnosis and treatment; expert, unencumbered healthcare and care giver support; and access to affordable health insurance coverage.

The true strength of our Foundation efforts has and will continue to derive its strength from an international network of chapters and people who in some way are connected to these rare diseases. Individuals that can tell their stories and demonstrate why much more can and will done.

There is enormous dedication and commitment by our board of directors, medical advisory board, our national headquarters' team, volunteers, donors, fellow patient advocate groups and industry friends that continues to support our efforts in a professional and generous sign of faith.

Above: Estelle Benson (pictured left) established the Foundation 12 years ago. Today, she remains a guiding force in its mission.
Below: The Foundation's headquarters are located in Narberth, PA, just outside of Philadelphia, and is staffed by: (from left) Camille Yee, Shawn Coats, Paricia A. Bryant and Cheryl Cloutman.

Please share any final thoughts about your work and the Foundation's mission.

Since the Foundation was started in 1988 by Estelle Benson, it has never wavered from its mission to improve the quality of life for individuals and families worldwide. When Estelle's husband, Robert, was diagnosed with GBS, little was known about the disease and there were no support groups or organizations in existence to help people cope with treatment issues and the physical and emotional problems that patients and caregivers experience when faced with a rare disease. Estelle took on the challenge. Under her outstanding leadership, a small group of eight people around a dining room table grew into 174 chapters in 22 countries with more than 30,000 members. I am honored to be following in her footsteps!

Kym Kilbourne *is PPTA's Assistant Director, North America Communications*

DANCE STEP DIAGRAM/ISTOCK

STAFF

John Delacourt

MY NAME IS JOHN DELACOURT.
I am PPTA's Senior Director, Legal Affairs. Although I joined PPTA in January, I am not really new to the Association. From 2006 to 2009, I served as PPTA's outside counsel with the law firm of Kelley Drye & Warren LLP. Because I am already familiar with many of the industry's personalities and issues, the transition has been smooth, though I am sure there is still much to learn.

As Senior Director, Legal Affairs, I am PPTA's chief legal officer. This means that I am responsible for counseling Association personnel on day-to-day legal compliance, as well as for managing the Association's litigation and legal advocacy efforts. Currently, much of my time is dedicated to PPTA's antitrust compliance programs. However, I also hope to contribute to the Association's positive mission—in such areas as U.S. Food and Drug Administration/European Medicines Agency regulation, healthcare reimbursement, and trade liberalization—by adding a strong legal component to PPTA's ongoing efforts in both North America and Europe.

Tell us about your background.
I am originally from southeastern Michigan, but moved to Washington, D.C. to attend college at Georgetown University. I left the Washington area briefly to complete my legal education at Harvard Law School, but returned after graduation to enter private law practice. While in private practice, I worked primarily in the areas of antitrust and intellectual property litigation, including a handful of matters involving pharmaceutical and biotechnology products.

In 2001, I was presented with an opportunity to work with Chairman Timothy Muris at the Federal Trade Commission (FTC). I accepted the offer, and began work with the Office of Policy Planning (OPP)—an FTC sub-unit within the Chairman's Office charged with implementing the Chairman's policy priorities. I eventually became OPP's Assistant Director, and ultimately rose to the position of Chief Antitrust Counsel. While with OPP, I worked on a broad range of antitrust issues, including pharmaceutical "reverse payment" settlements, legal barriers to the expansion of e-commerce, and anticompetitive "gaming" of regulatory processes in the healthcare and energy sectors.

In 2006, I left the FTC to join the Collier Shannon law firm, which had served as outside counsel to PPTA for many years. Soon thereafter, Collier Shannon merged with Kelley Drye. Although the merger changed many things, the firm's representation of PPTA was not one of them. I continued to work with PPTA throughout my tenure with Kelley Drye, focusing primarily on antitrust compliance. Not surprisingly, given the breadth of PPTA's activities, working with the Association also provided me with the opportunity to advise in other areas, including consumer privacy, product liability, and—on at least one occasion—constitutional analysis.

My wife, Tarah, is also an attorney, and works at Hogan Lovells LLP. We have one daughter, Victoria, who is just a few months shy of one year old. Victoria is an absolute delight and, thankfully, has no interest in discussing legal issues.

What is your proudest professional achievement?
Perhaps the most successful initiative I was involved in at the FTC was the Commission's E-Commerce Task Force. As a member of the Task Force, I was charged with identifying and challenging so-called "legacy laws"—laws enacted prior to the emergence of the Internet—that hurt consumers by disadvantaging e-commerce competitors. The Task Force used a variety of legal tools to challenge laws restricting, and outright prohibiting, Internet sales of everything from contact lenses to funeral

caskets. Even the Supreme Court took notice and, in its landmark decision striking down bans on interstate shipments of wine, cited the Task Force's report on the subject multiple times.

Obviously, the specific issues that PPTA deals with are quite different, but I think the principle is the same. Although plasma therapies are hardly the newcomer that e-commerce was in the early 2000s, many regulators and policymakers are still not as familiar with the industry as they should be. Consequently, they often resort to old methods and approaches, developed in the context of chemical pharmaceuticals, that no longer fit. Identifying opportunities to use the legal process to educate key decision-makers, and to inform them of the adverse consequences for both patients and manufacturers of applying a "Big Pharma" mindset across the board, is a big part of the role that I hope to play with PPTA.

What is most rewarding about working in this industry?

Despite the fact that, as an attorney, I am not really involved in the technical side of the business, I find the science underlying the production and use of plasma therapies fascinating. Prior to working with PPTA, the most interesting matter I had worked on was a patent infringement case involving biotechnology in corn seeds. It was amazing, and humbling, to me that human beings could, in essence, change the rules at such a fundamental level. Of course, this is all in a day's work for PPTA's member companies, only at a more profound level because their breakthroughs affect actual human lives. It is very rewarding for me to be able to play even a small role in facilitating this important work.

UPCOMING CONFERENCES & SYMPOSIUMS EVENTS 2010

March 9 – 12	International Symposium on Intensive Care and Emergency Medicine *Brussels, Belgium*
March 13 – 14	2nd Pan-European Conference on Haemoglobinopathies *Berlin, Germany*
March 13 – 15	5th European Conference on Rare Diseases *Krakow, Poland*
March 16 – 17	International Plasma Protein Congress 2010 *Berlin, Germany*
March 18 – 20	VI International Conference on Rare Diseases and Orphan Drugs (ICORD 2010) *Buenos Aires, Argentina*
April 22 – 24	Inaugural AESEAN Federation of Haematology Scientific Meeting *Kuala Lumpur, Malaysia*
May 22 – 25	International Society on Thrombosis and Haemostasis SCC Meeting *Cairo, Egypt*
May 26-27	International Plasma Fractionation Association (IPFA)/PEI 17th Workshop on "Surveillance and Screening of Blood Borne Pathogens" *Zagreb, Croatia*
June 10 – 13	15th Congress of the European Hematology Association *Barcelona, Spain*
June 15-16	Plasma Protein Forum *Reston, Virginia, United States*
June 26 – July 1	XXXIst International Congress of the ISBT *Berlin, Germany*
July 10 – 14	Hemophilia 2010 World Congress *Buenos Aires, Argentina*
August 22 – 27	14th International Congress of Immunology *Kobe, Japan*
October 7 – 10	XIVth Meeting of the European Society for Immunodeficiency *Istanbul, Turkey*
October 8 -10	European Haemophilia Consortium Annual General Meeting *Lisbon, Portugal*
October 9 – 12	AABB Annual Meeting *Baltimore, Maryland, United States*
October 10	Source Business Forum *Baltimore, Maryland, USA* PPTA Members Only
October 21 -24	XI European Symposium on Platelet and Granulocyte Immunobiology *Beaune, France*

INSIDE PPTA

PPTA MEMBER NEWS
FROM AROUND THE GLOBE

IN MEMORIAM

On the morning of December 18, 2009 my assistant, Dottie Tripp, passed away. In the recent addition of *The Source,* she openly discussed that she had been diagnosed with cancer. Dottie was an enormous example and inspiration to those who worked with her in showing how to deal with such a difficult situation. Dignity and courage is what we saw. She did not give up until she knew it was time for her to leave us. She had accepted it.

The last evening of her life, my wife, Rose, and I visited her in her home. We held and kissed her and spoke about the PPTA staff. A big smile was her response.

Dottie was the first to send me her self assessment of the annual performance review. She wrote:

"In spite of a challenging year,
I believe I have been able to maintain quality support
to the President, PPTA, members and other PPTA staff."

She sure did. May she rest in peace. —Jan M. Bult

PPTA LAUNCHES EUROPEAN SOURCE INDUSTRY IMAGE CAMPAIGN

PPTA recently launched the European Source Image and Credibility Campaign, with an in person meeting of the European Source Image Task Force in Frankfurt, Germany on January 12. There are plans to utilize new media to advertise the need for plasma donations in a manner similar to the Facebook campaign, which successfully ran in the first quarter of 2009 in the U.S. In addition, a German language version of www.donatingplasma.org will be created to provide educational information to donors in Germany and Austria regarding plasma donation. A video of the plasma donor experience is in the works as well in order to further demystify this process for potential

Frankfurt, Germany

GLOSSARY OF TERMS

CDMS	Cross Donation Management Standard
CIDP	Chronic Inflammatory Demyelinating Polyneuropathy
CJD	Creutzfeldt Jakob Disease
DHQ	Donor History Questionnaire
DG	Directorate-General
EID	Emerging Infectious Diseases
EMEA	European Medicines Agency
EMG	Electromyography
ER	Emergency Room
FDA	U.S. Food and Drug Administration
FTC	Federal Trade Commission
GBS	Guillain-Barre Syndrome
GDP	Gross Domestic Product
IPPIA	International Plasma Protein Industry Association
IPOPI	International Patient Organisation for Primary Immunodeficiencies
IQPP	International Quality Plasma Program
IVIG	Intravenous Immune Globulin
MRI	Magnetic Resonance Imaging
PID	Primary Immunodeficiency Disease
PSSC	Pathogen Safety Steering Committee
QSEAL	Quality Standards of Excellence, Assurance and Leadership
SARS	Severe Acute Respiratory Syndrome
vCJD	Variant Creutzfeldt Jakob Disease
WHF	World Hemophilia Federation
WHO	World Health Organization
WNV	West Nile Virus
WTO	World Trade Organization

ILLUSTRATION: ROSE BULT, PHOTOGRAPH: VENI / ISTOCK

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See us at:

Plasma Protein Forum,
Reston, VA, USA
June 15 & 16 2010

PPTA
Plasma Protein Therapeutics Association

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donors that will have multiple uses. This video content will be used online and also available in a format that can be distributed to interested potential donors at plasma collection centers and other venues. There are plans in the U.S. to continue the well-received initiatives that began in 2009. New media advertisements will run in 2010 and awareness campaigns will run in states, creating positive press on lifesaving plasma protein therapies and the many people in communities who benefit from these medicines.

U.S. HEALTH CARE REFORM EFFORTS STALLED, FALTERING ECONOMY AND JOBS BILL TAKING PRECEDENCE

President Obama scheduled a bipartisan health reform summit for February 25 in efforts to regain momentum in overhauling America's health care system. However, Republicans, revitalized with the recent Gubernatorial and Senatorial victories as well as recent announcements of numerous Congressional Democrats not seeking reelection in 2010, are committed to the President's summit only if the current health reform measures coming out of Congress are scrapped. To this end, skeptics describe the summit as a eulogy for health care reform while proponents hope that the televised summit will show detractors as obstructionists.

Health care reform remains at an impasse. However, some suggest the most viable way forward for proponents would be for the House to clear the Senate's health care bill (HR 3590), and for the Senate to pass a package of changes to it using the filibuster-proof reconciliation process. That set of changes would incorporate the deals struck with the House, which would then send the new package to the White House. President Obama would first sign the original Senate bill, and then the "corrections" package.

The last measure signed into law would be the one that dictates the final shape of the overhaul. To this end, PPTA is exploring how the association's legislative priorities will fare in the event that the reconciliation process is successful. As the Senate "Byrd" rule dictates, no measure, no matter how small, can be included in the budget reconciliation bill if it is extraneous to savings or outlays in the budget. Therefore, issues like the Medicaid drug rebate increase and 340B expansion to the inpatient setting would be germane to the budget, however, insurance reforms, including eliminating preexisting conditions and annual/life time caps on the insured will not likely be included in the budget reconciliation bill. Again, PPTA is continuing its efforts on Capitol Hill to make sure that any final health reform measure includes unfettered patient access to plasma protein therapies.

Legislation that would extend for six months the enhanced Medicaid payments Congress granted to states under the American Recovery and Reinvestment Act (ARRA) may be added to the jobs bill during Senate floor debate in the coming weeks. Stakeholders had urged senators to include the $23.5 Billion provision in the underlying jobs bill, but the policy was not included in the draft bills. Senate leadership introduced a stand-alone bill that would extend the states' enhanced Medicaid payments for an additional six months. Extending the federal matching dollars to a state's Medicaid program is important to the plasma protein therapies' user community because without the additional funds, budget strapped states may be forced to scale back enrollment and services to Medicaid recipients that could lead to limiting access to therapies through prior authorization, step therapy or sole source contracts. .

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